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| 09/916,808 | 07/27/2001 | Mark John Gibbs | 10338-2U1 (2441651/VPA) | 2166 |
| 570 | 7590 | 12/04/2003 | EXAMINER CHAKRABARTI, ARUN K | |
| AKIN GUMP STRAUSS HAUER & FELD L.L.P. ONE COMMERCE SQUARE 2005 MARKET STREET, SUITE 2200 PHILADELPHIA, PA 19103-7013 | | | ART UNIT 1634 | PAPER NUMBER |

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/916,808

Applicant(s)
Gibbs

Examiner
Arun Chakrabarti

Art Unit
1634



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 29, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above, claim(s) 10-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/916,808.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1003 6) ☒ Other: Detailed Action

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DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group I, corresponding to claims 1-9, in Paper No. 1003 is acknowledged. The traversal is on the ground(s) that there is no burden to examine claims of Groups II and III along with claims of Group I. This is not found persuasive because as it is made clear in the restriction requirement that examination of Groups II and III will require the search of not only 2045 patents of Group I under the class 536, subclass 22.1 but also 11204 patents of Group II under the class 435, subclass 6 and in addition 600 patents of Group III under the class 700, subclass 90. This is prima facie evidence of the burden of search, which is not rebutted.

The requirement is still deemed proper and is therefore made FINAL.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process claim in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitation of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Specification

2. The claims 1 and 3-5 are objected to because of the following informalities: The word “hybridising” in claims 1 and 3-5 and the word “immobilised” in claim 6 are incorrect in spelling.

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Appropriate corrections are required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

4. Claims 1-4 and 6-8 are rejected under 35 U.S.C. 102 (e) as being anticipated by Austin et al. (U.S. Patent 6,132,965) (October 17, 2000).

Austin et al teaches a set of oligonucleotide probes for detecting a plurality of different target polynucleotides, wherein a respective target polynucleotide corresponds to a single polynucleotide or a group of related polynucleotides, the set including a collection of different promiscuous probes, wherein a respective promiscuous probe is capable of hybridizing to a target sequence shared between at least two of the target polynucleotides, wherein at least one target polynucleotide comprises at least two target sequences shared between other target polynucleotides, and wherein a predefined combination of promiscuous probes is capable of

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hybridizing to the at least two target sequences, the predefined combination providing specificity of detection of the at least one target polynucleotide (Column 11, lines 15-30 and Figure 5 and Column 12, lines 11-40).

Austin et al teaches a set of oligonucleotide probes, comprising a plurality of different predefined combination of probes, each providing specificity of detection of a different target polynucleotide (Column 11, lines 15-30 and Column 12, lines 11-40).

Austin et al teaches a set of oligonucleotide probes, further comprising at least one non-promiscuous probe that is capable of hybridizing to a unique target sequence of a single target polynucleotide (Column 11, lines 15-30).

Austin et al teaches a set of oligonucleotide probes, comprising at least one probe that is capable of hybridizing to a pivot sequence, which divides two or more polynucleotides into distinct groups (Column 11, lines 15-30).

Austin et al teaches a set of oligonucleotide probes, wherein the probes are immobilized on a solid support (Column 11, lines 20-23 and Column 12, lines 11-20).

Austin et al teaches a set of oligonucleotide probes, wherein the probes are in the form of a high-density nucleic acid array (Column 11, lines 20-23).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being obvious over Austin et al. (U.S. Patent 6,132,965) (October 17, 2000) in view of Pfahl (U.S. Patent 6,335,159 B1) (January 1, 2002).

Austin et al. teaches the set of oligonucleotide probes of claims 1-4 and 6-8 as described above.

Austin et al does not teach a set of oligonucleotide probes, comprising at least one degenerate oligonucleotide probe which is capable of hybridizing to a redundant target sequence.

Pfahl teaches a set of oligonucleotide probes, comprising at least one degenerate oligonucleotide probe which is capable of hybridizing to a redundant target sequence (Column 5, lines 21-51).

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It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a set of oligonucleotide probes, comprising at least one degenerate oligonucleotide probe which is capable of hybridizing to a redundant target sequence of Pfahl into the method of Austin et al., since Pfahl states, "In certain circumstances, one of skill in the art may find it desirable to prepare probes that are fairly long, and/or encompass regions of the amino acid sequence which would have a high degree of redundancy in corresponding nucleic acid sequences, particularly if this lengthy and/or redundant region is highly characteristic of the receptor protein (Column 5, lines 34-40)." An ordinary artisan would have combined and substituted a set of oligonucleotide probes, comprising at least one degenerate oligonucleotide probe which is capable of hybridizing to a redundant target sequence of Pfahl into the method of Austin et al., in order to improve the preparation of effective probes. An ordinary practitioner would have been motivated to combine and substitute a set of oligonucleotide probes, comprising at least one degenerate oligonucleotide probe which is capable of hybridizing to a redundant target sequence of Pfahl into the method of Austin et al. in order to achieve the express advantages, as noted by Pfahl, of an invention which provides probes that are fairly long, and/or encompass regions of the amino acid sequence which would have a high degree of redundancy in corresponding nucleic acid sequences, particularly if this lengthy and/or redundant region is highly characteristic of the receptor protein.

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7. Claim 9 is rejected under 35 U.S.C. 103(a) as being obvious over Austin et al. (U.S. Patent 6,132,965) (October 17, 2000) in view of Krull et al. (U.S. Patent 6,503,711 B1) (January 7, 2003).

Austin et al. teaches the set of oligonucleotide probes of claims 1-4 and 6-8 as described above.

Austin et al. does not teach the set of oligonucleotide probes, wherein the probes are linked to the support via a spacer.

Krull et al. teaches the set of oligonucleotide probes, wherein the probes are linked to the support via a spacer (Example 2, column 27, lines 11-67).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the set of oligonucleotide probes, wherein the probes are linked to the support via a spacer of Krull et al. into the method of Austin et al., since Krull et al. state, "For the purpose of creating biosensors with higher sensitivity and lower detection limits, this method is advantageous over the use of hydrocarbon tethers. The water soluble HEG linker will provide a more fluid environment (which should not self-assemble) so as to improve the ability of the immobilized DNA strands to hybridize with complementary material in solution (in terms of energetics and kinetics) (Column 27, lines 22-29)." An ordinary artisan would have combined and substituted the set of oligonucleotide probes, wherein the probes are linked to the support via a spacer of Krull et al. into the method of Austin et al., in order to improve the preparation of biosensors. An ordinary practitioner would have been motivated to

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combine and substitute the set of oligonucleotide probes, wherein the probes are linked to the support via a spacer of Krull et al. into the method of Austin et al., in order to achieve the express advantages, as noted by Krull et al., of an invention which is advantageous over the use of hydrocarbon tethers for the purpose of creating biosensors with higher sensitivity and lower detection limits and which also provides a more fluid environment (which should not self-assemble) so as to improve the ability of the immobilized DNA strands to hybridize with complementary material in solution (in terms of energetics and kinetics).

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose current telephone number is (703) 306-5818. This telephone number will be changed on and from January 13, 2004 to (571)-272-0740.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group LIE Chantae Dessau whose telephone number is (703) 605-1237.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 is (703) 872-9306. Please note that the faxing of such

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papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30

(November 15, 1989).

Arun Kr. Chakrabarti
ARUN K. CHAKRABARTI
PATENT EXAMINER
Arun Chakrabarti
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November 20, 2003

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